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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,825	08/04/2005	Eliseo Quintanilla Almagro	PRT 3011	7452
30868	7590	04/03/2006	EXAMINER	
KRAMER & AMADO, P.C. 1725 DUKE STREET SUITE 240 ALEXANDRIA, VA 22314			ALONIS, MELENIE LEE	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/516,825	Applicant(s) ALMAGRO, ELISEO QUINTANILLA	
	Examiner Melenie Alonis	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-9 are presented for examination on the merits

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. The title contains the word "novel". A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 8 is objected to because of the following informalities: the phrase "extracts comprises" is recited. This is improper use of the English language. Appropriate correction is required.

Claims 4-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend directly or indirectly from another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 101

Art Unit: 1655

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an extract obtained from *Polypodium leucotomas*, does not reasonably provide enablement for extracts which are obtained from the large number of species which are part of the *Polypodium* genus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that an extract obtained from a particular species of *Polypodium* (*Polypodium leucotomas*) may be useful for the intended uses instantly claimed (i.e. treating fibrotic

Art Unit: 1655

diseases). However, the claims encompass using any and all extracts from the Polypodium genus of plants for such purpose. This is clearly beyond the scope of the instantly claimed/disclosed invention, as applicants have not disclosed that they have tested extracts from any and all plants in the Polypodium genus for their efficacy in treatment of fibrotic diseases. It should be noted that there are 75 species of plants in the Polypodium genus (as referenced by raintree-health). It would not be expected that extracts from the rhizomes of all 75 species of Polypodium would have the same characteristics and therapeutic effect.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare the instantly claimed Polypodium extracts for use to treat fibrotic diseases from among the large number of Polypodium species encompassed by the instant claims. .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the polypodium extracts" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1655

Claims 1-9 provide for the use of polypodium extracts, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-5 of U.S. Patent No. 5,601,829.

Although the conflicting claims are not identical, they are not patentably distinct from each other because: the instant claims are drafted so broadly that they read on the

Art Unit: 1655

invention of U.S. 5,601,829. As currently drafted, is not clear if the instant claims are drawn to a method of use of an extract of Polypodium leucotomas obtained from rhizomes, or to the extract itself. The invention of U.S. 5,601,829 is drawn to a method of using an extract of polypodium leucotomas obtained from rhizomes to produce neuroprotective effects. This method of use in U.S 5,601, 829 reads on the instantly claimed invention, because, despite the intended use, the extract is assumed to be the same product. Consequently, the effects of the extract would inherently be the same.

With respect to the art rejection(s) below, please note that the claims have been examined over the art insofar as they read upon a product - i.e., a Polypodium extract including a Polypodium leucotomos extract.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by McCan et al, US 3,395,223.

Art Unit: 1655

Although difficult to interpret as currently drafted, a Polypodium extract obtainable using a solvent having a dielectric constant of more than 20, and being obtainable by extraction with means for dissolving water soluble compounds is claimed.

McCan et al, teach a method of obtaining a Polypodium extract using a polar solvent such as methanol for extraction (see for example column 2, line 17). Please note that, as readily admitted by applicant (see, e.g. specification, p.6), methanol inherently has a dielectric constant of greater than 20. McCan et al. further teach that the extract obtained contains water-soluble components (see, e.g. column 1, lines 59-68).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Delgado de Chang EP0 503,208A1.

Although difficult to interpret as currently drafted, a Polypodium extract which is obtained from the rhizomes of Polypodium leucotomas, which is obtainable by extraction using a solvent having a dielectric constant more than 20, with a means for dissolving water soluble compounds, which comprises lactic, fumaric, quinic, citric, or malic acid, and is administered orally is claimed.

Delgado de Chang teaches a water soluble extract from the rhizomes of Polypodium (including Polypodium leucotomas) (see, e.g., p. 2, lines 4-5 and p. 4 line 6). Delgado de Chang further teaches that the extract is obtained by use of a solvent with a dielectric constant greater than 20 (see, e.g., p. 4, line 23). Delgado de Chang

further teaches that this extract may be in the form of a pill or capsule for oral administration (see. e.g., p.5, lines 1,7). Delgado de Chang also teaches the extract obtained contains acids, which can be detected by chromatographic and spectroscopic methods (See. e.g., p. 4, lines 47-48). Further, please note that the rhizome extract (obtained using the same solvent) taught by the cited reference would inherently comprise one or more of the particular instantly claimed, naturally-occurring acids therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delgado de Chang EP0 503,208A.

A Polypodium extract which is obtained from the rhizomes of Polypodium leucotomas, which is obtainable by extraction using a solvent having a dielectric constant more than 20, with a means for dissolving water soluble compounds, which comprises lactic, fumaric, quinic, citric acid, or malic acid, and is administered orally is claimed.

Delgado de Chang beneficially teaches a therapeutic water soluble extract obtainable from the rhizomes Polypodium leucotomas, as discussed in detail above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic, water soluble extract from the rhizome of *Polypodium leucotomas* based on the beneficial teachings provided by Delgado de Chang. The adjustment of particular conventional working conditions (e.g. making the extract into one particular oral form thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

With respect to the art rejections above, it is noted that the reference does not teach that the extract composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie Alonis whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melenie Alonis
Art Unit 1655



CHRISTOPHER R. TATE
PRIMARY EXAMINER